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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,515	03/01/2002	Jeffrey Braman	25436/1232	2153

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EXAMINER

RILEY, JEZIA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/086,515

Applicant(s)

BRAMAN ET AL.

Examiner

Jezia Riley

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-105 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-105 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 10, 19, 28, 37, 46 are vague and indefinite because in claim 1, for example, it is disclosed that X is a leaving group but the formula does not comprise "X" moiety. The formula comprises only "X1" and "X2" moieties, which are defined as being the same or different which is also unclear because there is no definition of specific moieties for said X1 and X2. The confusion is that it is unclear if X is part of X1 and X2 or a totally different moiety.

Claim Objections

2. Claims 2, 11, 29, 38, 65, 74, 83 are objected to because of the following informalities: the group "No₃" should be written "NO₃". Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 55-63, 73-81, 91-105 are rejected under 35 U.S.C. 102(b) as being anticipated by Houthoff (WO 98/15564).

Houthoff discloses methods for labeling nucleotides which involves using linker platinum compounds. The formula (I) in page 3 is viewed to be inclusive of the instant invention wherein X represents any stabilizing bridge and wherein A and B are the same or different reactive moieties. The linker compounds comprises X which represents an aliphatic diamine having 2-6 carbon atoms, which is viewed to be inclusive of cyclohexyl moieties for example. (page 7-8). The coupling or reactive moieties A and B are selected from halogens, NO₃ and SO₃. (page 8). The labels may be radioactive, enzymes, specific binding pairs, fluorophores (page 4). The preparation of said compounds include the reaction of potassium tetrachloroplatinate with the diamine derivatives (page 13). Pages 22-26 describe the techniques which include attachment of polynucleotide sequences to solid phase which is viewed to be inclusive of nucleic acid arrays.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houthoff (WO 98/15564) in view of Lippard et al. (4,843,161).

Houthoff discloses methods for labeling nucleotides which involves using linker platinum compounds. The formula (I) in page 3 is viewed to be inclusive of the instant invention wherein X represents any stabilizing bridge and wherein A and B are the same or different reactive moieties. The linker compounds comprises X which represents an aliphatic diamine having 2-6 carbon atoms, which is viewed to be inclusive of cyclohexyl moieties. (page 7-8). The coupling or reactive moieties A and B

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are selected from halogens, NO₃ and SO₃. (page 8). The labels may be radioactive, enzymes, specific binding pairs, fluorophores (page 4). The preparation of said compounds include the reaction of potassium tetrachloroplatinate with the diamine derivatives (page 13). Pages 22-26 describe the techniques which include attachment of polynucleotide sequences to solid phase which is viewed to be inclusive of nucleic acid arrays.

Lippard et al. discloses a compounds of Formula (I) which comprises dichloroethylenediamine-platinum having a linker attached to the ring nitrogen said linker is attached to a label. Said compounds are used to bind to specific sites of the nucleotide forming a DNA (col 1-3). This invention provides novel anticancer drugs comprising a DNA intercalative drug chemically linked to a platinum anticancer drug in order to form a single molecule which can be administered to a patient. Preferred molecular bridges are an alkyl chain, polyamine chain, polyether chain or the like, which can be of variable length and composition which is viewed to be inclusive of the aromatic ring of instant claim 1 for example.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use platinum compounds comprises label attached either to ring nitrogen via a linker as taught by Lippard. Said compounds are useful for labeling and intercalative drugs. The motivation is that it has been found that the compounds of Lippard are more highly water-soluble than the counterpart unmodified platinum drug, and that they are toxic toward tumor cells which are resistant to the unmodified


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platinum antitumor drug when administered alone. The intercalative drug and the platinum anticancer drug are joined together by a molecular bridge which does not adversely affect the activity of either the intercalative drug or the platinum drug against tumor cells (Lippard col. 1).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



JEZIA RILEY
PRIMARY EXAMINER

June 17, 2003